UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,795	04/21/2004	Eckard Weber	OREX.001A	5046

20995 7590 06/11/2007

KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
KWON, BRIAN YONG S	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
06/11/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/828,795	WEBER ET AL.	
	Examiner	Art Unit	
	Brian S. Kwon	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 May 2007 & tele. interview on 6/1/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-11,24-26,29-31 and 34-49* is/are pending in the application.

4a) Of the above claim(s) *10,11,24-26,29-31,34,35,44 and 45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-9, 36-43 and 46-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *05/07/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Upon further consideration, the examiner **withdraws the finality of the rejection of the last Office action**, and issues a new ground of rejection in this Office Action. Furthermore, the examiner vacates the Advisory Action mailed 05/29/07 and enters an amendment filed May 07, 2007.

2. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of actions being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8, 36 and 48-49 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses naltrexone and bupropion as a suitable example of first compound and second compound respectively, which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, the claims are directed to encompass "prodrug thereof" which only corresponds in some undefined way to specifically instantly disclosed chemicals. None of these meet the written description provision of 35 USC

112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompasses a myriad of possibilities. To the extent that no structure function data is disclosed in connection with theses functionally described compounds to correlate, or there is not disclosed correlation established between these functional drugs and the contemplated desired therapeutic effect to be achieved in practicing the instant invention, the specification provides insufficient written description to support the genus encompassed by the claims.

Vas-Cath Inc. Mahurkar, 19 USPQ2d 1111, makes clear the "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of "naltrexone or a pharmaceutically acceptable salt thereof" and "bupropion or a pharmaceutically acceptable salt thereof, the skilled artisan cannot envision the detailed chemical structure of the encompassed prodrugs, derivatives, analogs, etc., regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966(1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)* ("[T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.") Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.*

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 8 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "said compound comprises bupropion". The term "compound" refers to a single entity and cannot contain additional elements as the applicant alleged by reciting open-ended phrase "comprises". This inconsistency leaves the reader in doubt as to the meaning of the

invention to which they refer, thereby rendering the definition of the subject-matter of said claims unclear.

Suggest rewording of "comprises" to "is".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 8-9, 36-43 and 48-49 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Malley et al. (US 6004970).

O'Malley discloses a composition comprising an opioid antagonist (i.e., naltrexone) in combination with nicotine and antidepressant (i.e., bupropion hydrochloride) that is useful for the treatment of smoking cessation, wherein said composition is prepared and administered in various dosage forms including sustained release preparation, oral, intravenous, intramuscular or intradermal, e.g., by sterile injections, including depot versions, implants, parenteral administration; wherein naltrexone is administered in 2 to 10mg (bolus), 0.2 to 1.0 mg/hr (a continuous drip) or 25 to 100mg (oral); and wherein said composition is delivered in a sustained release preparation (column 2, line 66 through column 3, line 17; column 3, lines 58-67; column 4, lines 18-26; column 5, lines 27-33; column 6, lines 1-14; and claims 11-13 and 16-17).

With respect to the specific amounts of bupropion, "about 30mg to about 300mg", in claims 39-43, the examiner determines that such amounts deems to be inherent to the known

antidepressant amount or antismoking cessation amount of bupropion (see column 4, lines 32-38 of USP 6197827 for your reference: USP'827 discloses a range of about 50 mg to about 300 mg per day of bupropion as antidepressant amount or antismoking amount). Therefore, O'Malley anticipates the claimed invention.

With respect to the instantly claimed "a weight loss affecting amount", since the referenced amounts of naltrexone and antidepressant amount of bupropion overlap with the instant "weight loss affecting amount" of naltrexone and bupropion (which about 5mg to about 50mg of naltrexone and about 30mg to 300mg of bupropion), O'Malley anticipates the claimed invention.

With respect to the instantly claimed "wherein said bupropion, or pharmaceutically acceptable salt thereof, is a sustained release formulation", since the interpretation of the instant claims (given "broadest reasonable interpretation) allows for the inclusion of not only the existence of each of ingredient, naltrexone or bupropion, in separate or independent sustained release form, but also the existence of said naltrexone and bupropion combination in sustained release form, O'Malley's composition comprising naltrexone and bupropion in depot versions or implants "metes and bounds" the claimed invention.

Alternatively, in case the applicant's invention only limits to the presence of naltrexone or buproprion in said composition, in separate or independent sustained release form, the claims will be rejected under 35 USC 103(a) as followings.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 8-9, 36-43 and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Malley et al. (US 6004970) in view of applicant's admission of the prior art of record (para. [0100]), and further in view of Li (US 6589553) and Cook (US 6071918).

The teaching of O'Malley et al. has been discussed above 35 USC 102(b) rejection.

Applicant admits that various sustained-release materials have been established and are well known by those skilled in the art.

Li and Cook are being supplied as references to demonstrate the routine knowledge in preparing naltrexone and bupropion in controlled or sustained release formulation. Li also teaches an advantage of delivering bupropion in sustained release formulation for greater convenience and improving compliance (column 2, lines 41-45).

The teaching of O'Malley differs from the claimed invention in incorporating sustained release bupropion into said composition. To incorporate such teaching into the teaching of O'Malley, would have been obvious in view of Applicant's admission and/or USP'716 and USP'918 that the preparing bupropion in controlled or sustained release formulation is well known in the art.

One having ordinary skill in the art would have been motivated to make such modification, with the reasonable expectation of success, to extend the usage of the claimed composition by preparing said composition in sustained release formulation to accommodate patients' preference and needs where the compliance could be improved with effective and/or well tolerated dosage regimen.

As discussed above, there are general references indicating that pharmaceuticals generally may be delivered sustained release, as well as disclosing benefits or advantages to be

achieved by sustained release forms versus other modes of administration. Therefore, there exist general art accepted motivations for formulating drugs for sustained release formulation.

As discussed above, the applicant's statement of "the affecting weight loss" is not limited to the interpretation of the composition claims since such property or characteristic deems to be expected feature of the referenced composition (due to overlapping dosage amounts). Thus, the cited references in combination make obvious the instant invention.

Relevant Art of Record

7. The prior art made of record and not relied upon is considered pertinent to applicant's invention. Dante (US 5817665, USP 5512593 or USP 6034091) teaches a composition comprising naltrexone in combination with bupropion that is useful for the treatment of depression; Gadde et al. (US 7109198) teaches use of bupropion including sustained release for the treatment of obesity; and Chen et al. (US 6210716) teaches use of sustained release bupropion for the treatment of smoking cessation or depression.

Conclusion

8. No Claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718. The fax number for this Group is (571) 273-8300.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications may be obtained from Private PAIR only. For more information about PAIR system, see http://pair-direct.uspto.gov Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Brian Kwon
Primary Patent Examiner
AU 1614